

TABLE—EXPERIMENTAL USE PERMIT TOXICITY DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	Use Pattern		Test substance to support		Test Note No.
		Food	Nonfood	MP	EP	
870.4100	Chronic oral - rodent	R	NR	TGAI	TGAI	6
Developmental Toxicity and Reproduction						
870.3700	Prenatal Developmental toxicity - rat and rabbit, preferred	R	NR	TGAI	TGAI	7, 8
870.3800	Reproduction	R	NR	TGAI	TGAI	6
Mutagenicity Testing						
870.5100	Bacterial reverse mutation assay	R	NR	TGAI	TGAI	9
870.5300 870.5375	<i>In vitro</i> mammalian cell assay	R	NR	TGAI	TGAI	9, 10
870.5385 870.5395	<i>In vivo</i> cytogenetics	R	NR	TGAI	TGAI	9, 11

(d) *Test notes.* The following test notes apply to the data requirements in the table to paragraph (c) of this section.

1. Not required if test material is a gas or a highly volatile liquid.

2. Not required if test material is corrosive to skin or has a pH of less than 2 or greater than 11.5.

3. Required if the product consists of, or under conditions of use will result in, a respirable material (e.g., gas, vapor, aerosol, or particulate).

4. Required if repeated dermal exposure is likely to occur under conditions of use.

5. Required if the test material is an organophosphorus substance, which includes uncharged organophosphorus esters, thioesters, or anhydrides of organophosphoric, organophosphonic, or organophosphoramidic acids, or of related phosphorothioic, phosphonothioic, or phosphorothioamidic acids, or is structurally related to other substances that may cause the delayed neurotoxicity sometimes seen in this class of chemicals.

6. These studies are seldom required to support EUPs. They may be required if the dietary exposure for these EUPs occupies a large part, e.g., greater than 50%, of the reference dose.

7. The oral route, by oral intubation, is preferred unless the chemical or physical properties of the test substance or the pattern of exposure suggests a more appropriate route of exposure.

8. May be combined with the 2-generation reproduction study in rodents by utilizing a second mating of the parental animals in either generation.

9. At a minimum, an initial battery of mutagenicity tests with possible confirmatory testing is required. Other relevant mutagenicity tests that may have been performed, plus a complete reference list must also be submitted.

10. Choice of assay using either:

i. Mouse lymphoma L5178Y cells, thymidine kinase (tk) gene locus, maximizing assay conditions for small colony expression or detection;

ii. Chinese hamster ovary (CHO) or Chinese hamster lung fibroblast (V79) cells, hypoxanthine-guanine phosphoribosyl transferase (hgpert) gene locus, accompanied by an appropriate *in vitro* test for clastogenicity; or

iii. CHO cells strains AS52, xanthine-guanine phosphoribosyl transferase (xpert) gene locus.

11. The micronucleus rodent bone marrow assay is preferred; however, rodent bone marrow assays using metaphase analysis (aberrations) are acceptable.

[72 FR 60957, Oct. 26, 2007, as amended at 73 FR 75596, Dec. 12, 2008]

#### § 158.240 Experimental use permit data requirements for ecological effects.

All data for terrestrial nontarget organisms and aquatic nontarget organisms as described in § 158.243 must be submitted to support a request for an experimental use permit. No data for nontarget plant protection must be submitted to support a request for an experimental use permit.